PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Edwin Oscar Schraa; Maria del Carmen Esandi

Serial No.:

Filed: December 8, 2000

For: METHOD OF ADMINISTERING ADENOVIRUS

Examiner:

Group Art Unit:

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PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Attached to this Preliminary Amendment as Appendix A is a marked-up version of claims according to rule 1.1.121 (as amended). The office is respectfully requested to enter the present amendment prior to commencing the examination of this application. Following are the claims in version to be considered for examination:

1. A kit of parts for gene delivery to a recipient cell in a host, using a gene delivery vehicle to which a humoral response can be raised, comprising a nucleic acid comprising a gene to be delivered to said recipient cell and further comprising a second composition of a second gene delivery vehicle essentially identical to said first gene delivery vehicle, but preferably lacking said gene to be delivered.

2. A kit of parts according to claim 1, wherein said second composition is a vaccine and wherein said first composition is a composition for gene therapy.

3. A kit of parts according to claim 2, wherein said vaccine is to be administered at a time before said gene therapy composition at a moment in time sufficient for the host to raise a neutralising humoral response to said second gene delivery vehicle.

4. (Amended) A kit of parts according to claim 1, wherein said second gene delivery vehicle comprises a nucleic acid encoding an indifferent protein.

5. (Amended) A kit of parts according to claim 1, wherein a gene delivery vehicle is of adenoviral origin.

6. (Amended) A kit of parts according to claim 1, wherein said gene therapy composition comprises a number of first gene delivery vehicles above the number that can be neutralised by a humoral response of said host.

7. A method for delivering a gene of interest to a recipient cell in a host using a gene delivery vehicle comprising a nucleic acid comprising said gene of interest, said method comprising administering to a host a vaccine composition comprising a gene delivery vehicle lacking said gene to be delivered, allowing for a neutralising humoral response to be raised by said host to said gene delivery vehicle lacking said gene to be delivered and administering a composition for gene therapy comprising essentially the same gene delivery vehicle having a nucleic acid comprising said gene to be delivered in an amount greater than the amount which can be neutralised by said humoral response.

8. A method for avoiding or diminishing liver toxicity in a host of a gene delivery composition upon administration, comprising administering to a host a vaccine composition

comprising a gene delivery vehicle, preferably lacking said gene to be delivered, allowing for a neutralising humoral response to be raised by said host to said gene delivery vehicle lacking preferably said gene to be delivered and administering a composition for gene therapy comprising essentially the same gene delivery vehicle having a nucleic acid comprising said gene to be delivered in an amount greater than the amount which can be neutralised by said humoral response.

9. (Amended) A method according to claim 7, wherein said gene delivery vehicle is of adenoviral origin.

10. (Amended) A kit of parts according to claim 1 in the preparation of a pharmaceutical for the use as a pharmaceutical.

11. (Amended) Use of a kit of parts according to claim 1 in the preparation of pharmaceutical for the treatment of diseases associated with uncontrolled proliferation of cells in a host, such as tumors or autoimmune diseases.

12. (Amended) Use of a kit of parts according to claim 1 in the preparation of a pharmaceutical for the treatment of diseases associated with genetic defects in a host.

13. (Amended) A kit of parts according to claim 1, wherein said gene of interest is interleukin-3.

14. (Amended) A method for the preparation of a kit of parts according to claim 1, comprising preparing at least one gene delivery vehicle by inserting a gene of interest in a nucleic acid to be delivered to a host cell, packaging said nucleic acid in a vehicle capable of entering a host cell and bringing a resulting gene delivery vehicle in a medium suitable for administration to a host.

15. A method according to claim 14, wherein said nucleic acid is based on or derived from an adenovirus.

16. (Amended) A method according to claim 14, wherein said vehicle comprises adenoviral structural proteins.

17. A method according to claim 16, wherein at least one vehicle comprises proteins from adenoviruses of different serotypes.

18. (Amended) A method according to claim 15, wherein said nucleic acid comprises at least one ITR and a packaging signal based on or derived from an adenovirus.

19. (Amended) A method according to claim 15, wherein said nucleic acid does not encode functional structural adenoviral proteins.

20. (Amended) A method according to claim 15, wherein said nucleic acid encodes E2A adenoviral gene product.

21. A method according to claim 20, wherein said E2A gene product is temperature sensitive.

22. (Amended) A method according to claim 14, wherein said packaging occurs in a packaging cell.

23. A method according to claim 22 wherein said packaging cell is derived from or based on a primary cell.

24. A method according to claim 23, wherein said cell is based on or derived from PER.C6.

25. (Amended) A method according to claim 15 wherein said nucleic acid comprising said gene of interest is produced by a recombination step from two adenoviral vectors.

26. (Amended) A method according to claim 15, wherein said adenovirus is an adenovirus serotype 5 or serotype 35.

REMARKS

No new matter has been added. The Applicants request entry of the foregoing amendment prior to examination of the application on the merits.

Respectfully submitted,

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